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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,074	03/19/2001	Henry A. Lester	A-59891-2/RFT/JJD	8989

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/812,074

### Applicant(s)

LESTER ET AL.

### Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 13 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9-10-2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

1. Preliminary amendment filed March 30, 2004 has been entered. Claims 1, 13 and 39 are pending.

2. Applicant's election of Group II in the reply filed on March 30, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 1 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 30, 2004.

### ***Claim Objections***

3. Claim 13 is objected to because of the following informalities: Claim 13 is dependent on claim 7 which is cancelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 13 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is dependent on claim 7 which has been cancelled and thus is confusing and ambiguous. Claim 39 is dependent on claim 13 and thus encompass the same ambiguity.

Claims 13 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass a method of using a genus of nucleic acid probes which will hybridize with a large genus of nucleic acid which encodes variant inward rectifier potassium channel proteins which is not disclosed in the specification nor to one of skilled in the art. The probes are not defined by any critical or definitive structural limitations. Claims encompass DNAs which hybridize to the aforementioned genus of DNAs and encode proteins defined by function alone without any critical or definitive structural limitations because of no structural limitation and the recitation of "hybridization" language. The specification only discloses a single species disclosed in SEQ ID NO:1. The specification does not disclose what structural features, other than the full length sequence of the single species of SEQ ID NO:1, must be retained in order

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to render a protein as an inward rectifier potassium channel. The specification fail to disclose what specific functions are considered to be definitive of retinoic acid receptor and what specific structures are critical to their retention. The claims are drawn to a genus that need only be related or retain a function that is "characteristic" of a potassium channel without a definition of what functions are characteristic and what structures other than the full length sequence of SEQ ID NO:1 are required for said functions. Without said information, the single species cannot be representative of such a broad genus. Claimed method uses nucleic acid probes which encompass a large genus of probes from other potassium channel alleles or variants whose function has yet to be identified including from different species of animal because the structure of the newly identified naturally occurring channel is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. The essential feature of the invention is the single species of DNA encoding SEQ DI NO:2. The specification with a single species does not provide support for the claimed genus because *Eli Lilly* held that one skilled in the art could not envision the structure of the genus of proteins in other species such as human or the genus of mammalian or vertebrate proteins. In the same manner, one skilled in the art cannot envision the genus of potassium channel structure and thus the specification does not provide adequate disclosure for the claimed genus.

***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 13 and 39 of this application for the reasons provided above under the 35 USC 112 , first paragraph, above. See MPEP 706.02.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 13 and 39 are rejected under 35 U.S.C. 102(a), 102(b) , and 102(e) as being anticipated by Jan et al. (US 5,670,335).

Jan et al. disclose a method of isolating a sample using nucleic acid probes to hybridize with a sample (columns 6, 9, and 13-14). Jan et al. disclose SEQ ID NO :4 which is identical to applicant's SEQ DI NO:2.

6. Claims 13 and 39 are rejected under 35 U.S.C. 102(a) and 102(b) as being anticipated by Kubo et al. (Nature, 1993).

Kubo et al. disclose a method of isolating a sample using nucleic acid probes to hybridize with a sample (figures 1 and 4; page 85). Kubo et al. disclose SEQ ID NO :4 which is identical to applicant's SEQ ID NO:2.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jan et al. (US 5,492,825) is a cumulative reference with Jan et al. . (US 5,670,335).

Ho et al. (Nature, 1993) is a cumulative reference with Kubo et al. (Nature, 1993).

No claims are allowed.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
10 June 2004